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New York, NY 10023

EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT PAPER NUMBER

1634

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

10/073,781

Applicant(s)

CHANG ET AL.

Examiner

Jeanine A Goldberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-22 is/are pending in the application.
- 4a) Of the above claim(s) 9-15 and 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. This action is in response to the papers filed March 4, 2004. Currently, claims 1-22 are pending. Claims 9-15, 20-22 have been withdrawn as drawn to non-elected subject matter.
2. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow. This action is made FINAL.
3. Any objections and rejections not reiterated below are hereby withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-7, 16-19 are rejected under 35 U.S.C. 102(a) and 102 (e) as being anticipated by Knapp et al. (US Pat. 6,235,471, May 2001).

Knapp et al. (herein referred to as Knapp) teaches a device for hybridization which comprises a microfluidic channel comprising a first and second portion, an

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irregular cross section and a second portion with a probe, and a driving element.

Specifically, Knapp teaches a microfluidic system which has at least a first reaction channel and at least a first reagent introduction channel (col. 5, lines 5-10). Knapp teaches fluid can flow between the channels with a material transport system which may include micropumps, microvalves, fluid switches, for example (col. 5, lines 20-25)(limitations of Claim 1b). Knapp teaches that the reagent channel is a channel in any form such as a capillary, a trench, groove or the like (col. 10, lines 5-8)(limitations of Claim 3). Knapp teaches that "as fluid moves through a structure of varying cross sectional areas, its temperature will change, depending on the dimensions of the channel at any given point (col. 19, lines 60-65)(limitations of Claim 7). Knapp teaches that "a number of different channel geometries are effective in producing the nonthermal amplification devices and systems of the present invention" (col. 23, lines 36-41).

Knapp teaches a device fabricated into a solid substrate that includes a main analysis channel which comprises hybridization sites. The device also contains reservoirs connected by intersecting channels. Knapp teaches that when samples are double stranded genomic DNA, the sample may be denatured in a reservoir and moved into the main analysis channel (col. 32, lines 25-45). The reservoir and channel intersections comprise a widened channel, i.e. an irregular cross section, to facilitate mixing of the sample (col. 32)(limitations of Claim 1b, 2). The immobilization of oligonucleotides on solid substrates is carried out by any of a variety of methods (col. 32, lines 50-53)(limitations of Claims 4, 5, 6). Knapp teaches that sequential purification of the target portion of the genome can be achieved by selective hybridization (col.

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33)(limitations of Claim 8). The non-hybridized DNA is washed out of the main analysis channel (col. 34). Knapp teaches that in order to maximize the use of space on a substrate, serpentine, saw tooth or other channel geometries are used to incorporate longer channels on less substrate area to facilitate separation of reaction products or reactants (col. 42, lines 5-10). Knapp teaches that microfluidic devices are employed such that they utilize less space, have smaller reagent requirements, automatable which allows less human involvement and reduces error, contamination, and loss of material (col. 12, lines 20-30).

With respect to Claims 16-18, the device of Knapp and the instant device appear to have the same configuration, therefore, the device of Knapp would inherently be capable of producing shear stress. Alternatively, it is noted that shear stress may be affected by additional variables which are not influenced by the device itself. For example, velocity and viscosity of the fluid would affect the shear stress of the target molecules.

With respect to Claim 19, it is noted that the device comprises oligonucleotides which are complementary to different portions of a target sequence. Thus, the device comprises a second probe.

Response to Arguments

The response traverses the rejection. The response asserts that the cited art does not show or suggest that the channels of the microfluidic device should have a size and structure that would produce shear stress on target molecules. This argument has been reviewed but is not convincing because the instant claims and the instant

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specification do not specifically teach what size and structure would be required to produce shear stress. The apparatus of Knapp is directed to the use of space on a substrate, serpentine, saw tooth or other channel geometries are used to incorporate longer channels on less substrate area to facilitate separation of reaction products or reactants (col. 42, lines 5-10). The instant apparatus is depicted in the drawings as being serpentine in Figure 1. Therefore, since the apparatus' appear to be the same structure, Knapp's apparatus would be capable of producing shear stress on the target molecules. Furthermore, it is noted that shear stress is a quantity with units of pressure that is related to the strain rate experienced by fluid. The viscosity and velocity of the fluid affects the shear stress. Therefore, shear stress may be affected and increased by manipulating the fluid within the apparatus. Thus, the limitation would not materially affect the physical structure of the claimed apparatus. Changing the velocity and/or the viscosity of the fluid within the irregular cross section would produce shear stress on the target molecules in the fluid.

The response provides a Table to illustrates the differences between Knapp and the instant invention. The first row in the table is directed to purposes which does not affect the product claimed in the instant application. The intended use of the apparatus does not materially affect the apparatus, therefore it not persuasive.

The second row in the table is directed to components of the device. The instant device and the device of Knapp are each encompassed by the instant claims for the reasons set forth above. The final row of the table is directed to functions of the components of

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the device. Again, the intended use and function does not materially affect the product and therefore would not carry patentable weight.

Thus for the reasons above and those already of record, the rejection is maintained.

Conclusion

5. No claims allowable over the art.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

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Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Jeanine Goldberg
Patent Examiner
May 17, 2004


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600